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| EXAMINER | | | | |
| MEHTA, PARIKHA SOLANKI | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/649,214

Applicant(s)

JASCOB ET AL.

Examiner

PARIKHA S. MEHTA

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-50,54-58,60-67 and 69-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-50,54-58,60-67 and 69-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/5/09
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 50 is objected to because of the following informalities:
Claim 50 recites functional language unsupported by structure to produce such function.
Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 27-50, 54-58 and 60-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle et al (US Patent No. 6,285,902), previously made of record, hereinafter Kienzle ('902), in view of Sandstrom (US Patent No. 3,625,798), hereinafter Sandstrom ('798).

Regarding claims 27-29, 34, 35, 44-46, 54-56, 60-63, 68-72, 75, 76, 81 and 82, Kienzle ('902) teaches a system for use in navigating an instrument through an electromagnetic field including an instrument, a transmitter array that may be integrally formed or attached to a housing surrounding a C-arm (col. 10 lines 60-63, col. 11 lines 17-27), wherein the transmitters are used to localize the C-arm device during surgery (col. 8 lines 14-53). Kienzle ('902) shows the housing as extending outward from a mounting mechanism and surrounding a circumference of the intensifier and defining multiple openings about the perimeter of the housing (Fig. 4). Kienzle ('902) teaches of magnetically shielding the image intensifier (col. 10 lines 53-59), but does not specify that the housing is operable to substantially shield the imager from the field generated by the coil array, and therefore it is not clear whether the housing of Kienzle ('902) constitutes the shield as claimed in the instant application.

In the same field of endeavor, Sandstrom ('798) teaches a lead shield for an x-ray tube, the shield being operable to prevent interference caused by magnetic fields from affecting the imager (col. 1 line 50-col. 2 line 25). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Kienzle ('902) to manufacture the shield of lead in view of the teachings of Sandstrom ('798) in

order to achieve the presently claimed invention, as such a modification requires nothing more than the mere combination of prior art elements to yield predictable results, which has previously been held as unpatentable (see for precedent *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

Neither Kienzle ('902) nor Sandstrom ('798) teach a conically shaped shield. However, it has previously been held that, absent evidence that a particular shape of an element is significant to the operation of an invention, merely changing the shape of a prior art element is obvious and unpatentable over the prior art. Applicant has failed to disclose that a conical shape presents a significant and patentable improvement over the prior art square/rectangular shape. Accordingly, it would have been nothing more than an obvious matter of design choice for one of ordinary skill in the art at the time of invention to have chosen a conical shape for the shield of Kienzle ('902) and Sandstrom ('798).

Regarding claims 30, 32, 33, 47, 49, 50, 57, 58, 73, 74, and 85, although Kienzle ('902) does not expressly teach that the emitters comprise at least three orthogonal sets having three coils each, the Examiner hereby takes Official Notice that the use of three orthogonal localizing coils during surgical navigation is well known in the art. Furthermore, Kienzle ('902) broadly teaches of using at least three localizing emitters (col. 10 lines 60-62), which, when combined with the known prior art emitters comprising three orthogonal coils each, would result in the claimed invention.

Regarding claims 31 and 48, Kienzle ('902) broadly teaches that, in contrast to being integral to the housing, the emitters may simply be "attached" (col. 11 lines 21-24). It would have been an obvious matter of design choice to one of ordinary skill in the art at the time of invention to modify the system of Kienzle ('902), as previously modified by Sandstrom ('798), so as to attach the coils via an extension member in order to achieve the claimed invention.

Regarding claim 36, Kienzle ('902) teaches that the emitters may be repeatably attached to the C-arm (col. 10 lines 29-33). Repeatably attachment, as taught by Kienzle ('902), implies that the emitters are removably attached as claimed in the instant application.

Regarding claim 37, although Sandstrom ('798) does not require the shield to be integral with the imager, making a combination of prior art elements integral is not considered a patentable modification (see for precedent *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 Fed. Cir. 1983; see also MPEP § 2144 V).

Regarding claims 38, 39, 64, 77, Kienzle ('902) teaches the system to include a surgical tool with an electromagnetic sensor attached at the distal end (col. 7 line 66-col. 8 line 1, col. 9 lines 12-44). Although Kienzle ('902) does not specify that the surgical tool is non-rigid, such surgical tools (catheters, for example) are well known and widely used in the art of image-guided surgery.

Regarding claims 40, 41, 65-67, 78 and 79, Kienzle ('902) teaches the localizing system to use a variety of wireless methods to communicate with the various emitters of the surgical tool and C-arm (col. 9 lines 31-44).

Regarding claims 42 and 43, Kienzle ('902) teaches of using mathematical modeling to account for the effects of interference (col. 10 lines 53-59), and further teaches of storing potentiometer voltages on a memory for future access in a look-up table (col. 10 lines 10-12).

Regarding claim 80, the system of Kienzle ('902) includes a display operable to display navigation information (col. 8 lines 1-11).

Regarding claims 83 and 84, Kienzle ('902) teaches means for calibrating the localization system (col. 9 line 45 – col. 10 line 12).

Regarding claim 86, neither Kienzle ('902) nor Sandstrom ('798) teach the mounting mechanism to be an annular clamp. Such clamps, commonly referred to as "ring clamps", are well known and widely used in the art. It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Kienzle ('902) to substitute a ring clamp for the mounting mechanism shown in Figure 4, as a skilled artisan would expect the prior art device to work equally well with either mechanism (see for precedent *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

Response to Arguments

4. Applicant's arguments with respect to claims 27-50, 54-58, 60-67 and 69-86 have been considered but are moot in view of the new ground(s) of rejection.

5. Applicant has failed to adequately respond to the previous objection to claim 50, which is maintained and reiterated herein.

6. The previous double patenting rejection in view of US Patent No. 6,636,757 is hereby vacated in view of the Terminal Disclaimer filed on 31 January 2007. Examiner notes that no Terminal Disclaimer was filed on July 30, 2007 (Remarks p. 17).

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PARIKHA S. MEHTA whose telephone number is (571)272-3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Parikha S Mehta/
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